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| APPLICATION NO.                    | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|------------------------------------|---------------|----------------------|-------------------------|-----------------|
| 09/802,365                         | 03/09/2001    | Martha Jo Whitehouse | PP01671.003             | 8316            |
| 759                                | 90 07/02/2002 |                      |                         |                 |
| Chiron Corpora                     |               | EXAMINER             |                         |                 |
| Intellectual Prop<br>P.O. Box 8097 | erty          | PRASAD, SARADA C     |                         |                 |
| Emeryville, CA                     | 94662-8097    | ART UNIT             | PAPER NUMBER            |                 |
|                                    |               |                      | 1646                    |                 |
|                                    |               |                      | DATE MAILED: 07/02/2002 | 7               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del>- 4</del>  |                                    |  |  |  |  |  |
|---|------------------------------------|--|--|--|--|--|
|   | Application No.                    | Applicant(s)   |  |  |  |  |
| Office Acti n Summary   | 09/802,365                         | WHITEHOUSE, MARTHA JO                                |  |  |  |  |
| Onice Act in Summary  | Examiner                           | Art Unit   |  |  |  |  |
| The MAILING DATE f this communication app   | Sarada C Prasad                    | 1646   |  |  |  |  |
| Peri d for Reply  | ears on the cover sheet with the C | correspondence address                               |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |                                    |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>09 J</u>   | anuary 2002 .                      |  |  |  |  |  |
| 2a)  This action is <b>FINAL</b> . 2b)⊠ Thi   | s action is non-final.             |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disp sition of Claims   |                                    |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-29</u> is/are pending in the application.   |                                    |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                                    |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                                    |  |  |  |  |  |
| 6)☐ Claim(s) is/are rejected.   |                                    |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                                    |  |  |  |  |  |
| 8) Claim(s) <u>1-29</u> are subject to restriction and/or election requirement.  Application Papers   |                                    |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner  | ·                                  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accep  |                                    | miner.   |  |  |  |  |
| Applicant may not request that any objection to the   | •                                  |  |  |  |  |  |
| 11)☐ The proposed drawing correction filed on   | is: a) ☐ approved b) ☐ disappro    | oved by the Examiner.                                |  |  |  |  |
| If approved, corrected drawings are required in rep   | ly to this Office action.          |  |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |                                    |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                                    |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                                    |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |                                    |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                                    |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                                    |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |                                    |  |  |  |  |  |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |                                    |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                                    |  |  |  |  |  |
| Attachment(s)   |                                    |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal              | y (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |

## Restriction/Election

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

The claims drawn to a method for treating or preventing or improving erectile dysfunction in a patient require election of species as follows:

- (a) between the growth factors FGF, EGF, PDGF, VEGF, or TGF, and a second election of species, wherein
- (b) if FGF is elected, the applicant must further elect from species of FGF between SEQ ID Nos. 2, 4, 6, 8.

Election of species as stated above is required, because a method of treatment using FGF would not require administration of other growth factors such as EGF, or PDGF, or VEGF or TGF. Each of the species of 'growth factors' forms a patentably distinct invention, and would require non-cohesive searches, and consideration thus posing a burden on the Examiner to examine all of the species in a single application.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Having shown that these inventions are distinct for the reasons given above, they have acquired a separate status in the art as recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803).

Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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## **Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D. Examiner Art Unit 1646 June 17<sup>th</sup>, 2002

> YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600